

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.: 09/978,457
Filed: October 16, 2001
Group Art Unit: 3763
Examiner: Theodore J. Stigell
Applicant: Joseph J. Chang
Title: **SAFETY INTRAVENOUS CATHETER**
Attorney Docket: MDXVA-33DV (formerly 56301P579D)
Confirmation No.: 5126

DECLARATION OF JOSEPH J. CHANG UNDER 37 CFR § 1.131

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Joseph H. Chang, hereby declare and state:

1. I am the sole inventor named in the present application. I understand that the present application is a continuation of my earlier application Serial No. 09/476,429 filed December 30, 1999, and now issued as U.S. Patent No. 6,322,537 ("the parent case").
2. I have reviewed the claims as pending in the present application, as well as the claims as proposed to be amended or added to the present application as shown in Exhibit A attached hereto (collectively "my invention").
3. I conceived my invention prior to September 24, 1999, while I was working as an employee of Johnson & Johnson Medical, Inc. ("JJMI"). Attached as Exhibit B is a redacted copy of my Internal Invention Disclosure ("IID") to my employer JJMI disclosing my

invention. I signed the IID prior to September 24, 1999, and I had it witnessed, signed and dated by a fellow JJMI employee, also prior to September 24, 1999.

4. I believe that I and my then-employer acted with due diligence from a time prior to September 24, 1999 to the filing of the parent case on December 30, 1999. To that end, I submitted the IID through the normal channels within JJMI for consideration of my invention. I believe that the IID was handled and processed in at least the ordinary course and was ultimately turned over to outside patent counsel for preparation of a patent application thereon. After September 24, 1999, outside patent counsel forwarded a first draft to me for my review, and I worked with outside counsel to put the application into final form for filing as the parent case.

5. I understand that on or about December 29, 1999, Ethicon, Inc. merged into JJMI, and JJMI was renamed Ethicon, Inc. On December 30, 1999, the parent case was filed. An assignment was also filed assigning my invention to Ethicon, Inc., who is listed as the Assignee on the face of the parent case as issued.

6. All of the activities set forth in Paragraphs 3 and 4 above occurred in the United States.

7. Through a series of mergers and acquisitions, I understand that the parent case and the present application were assigned to Medex, Inc. who in turn has merged into Smiths Medical ASD, Inc. I have provided expert and related technical support to Medex, Inc. and/or Smiths Medical ASD, Inc. in connection with various patent litigations and oppositions in

relation to safety catheters, which is the field to which the invention pertains, and I have been compensated for my time thereon.

8. The statements made herein of my own knowledge are true, and all statements made on information and belief are believed to be true; further, these statements are made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

Date:

Sept. 12, 2007

By:

Joseph J. Chang

A handwritten signature in black ink, appearing to read "Joseph J. Chang", written over a horizontal line.

Listing of Claims:

1. (Currently Amended) An apparatus comprising:
- a needle cannula having a distal point, a proximal end and further having a shaft with a circumference;
- a tip protector having a base, the tip protector defining an opening to receive the needle cannula shaft and the tip protector is slideably mounted thereon;
- blocking means coupled to the tip protector for blocking the tip protector opening so as to enclose the distal point of the needle cannula within the tip [[top]] protector;
- a gasket coupled to the tip protector base defining an opening of a size to receive the needle cannula shaft;
- impeding means fixedly coupled to the needle cannula shaft at a predetermined location of the shaft for impeding movement of the tip protector along the needle cannula shaft beyond a pre-determined distance from the needle cannula distal point.
2. (Currently Amended) The apparatus of claim 1 further comprising a flash chamber coupled to the needle cannula at the needle [[needle]] cannula proximal end.
3. (Original) The apparatus of claim 1, wherein the gasket is formed in place at the tip protector base of an adhesive material.
4. (Original) The apparatus of claim 3, wherein the gasket adhesive material is selected from the group consisting of paraffin, polyester and polyamide.



5. (Original) The apparatus of claim 3, wherein the gasket adhesive material is cured by exposure to ultraviolet light.

6. (Original) The apparatus of claim 1 wherein the blocking means comprises:

a tab having a length sufficient to block the tip protector opening, the tab pivotably coupled to the tip protector within the tip protector opening and slideably engaging the needle cannula shaft in a first biased position such that upon removal of the needle cannula shaft the tab is free to pivot to a second position extending across the tip protector opening.

7. (Original) The apparatus of claim 1 wherein the impeding means comprises:

an irregularity in the needle cannula shaft circumference a pre-determined distance from the needle cannula distal point occluding passing of the needle cannula shaft through the gasket opening.

8. (Original) The apparatus of claim 6, wherein the tab is an anti-stick metal tab.

9. (Original) The apparatus of claim 7, wherein the irregularity is a crimp inscribed in the needle cannula shaft.

10. (Original) The apparatus of claim 6, wherein the tip protector further comprises:

a superstructure coupled to the base;

a cylindrical anti-stick metal clip housed within the superstructure defining an opening to receive the needle cannula shaft, the clip housing the tab, the tab disposed within the clip opening such that in its first position the tab is biased against the needle cannula shaft and in its second position the tab pivots to block the clip opening.

11. (Original) The apparatus of claim 10, wherein the tip protector is optically transparent, the cylindrical clip opening is a first opening, and the clip further defines a second opening extending over a portion of the cylindrical circumference exposing a portion of the first opening.

12.-14. (Canceled)

15. (New) An apparatus comprising:

a needle cannula having a distal point, a proximal end and further having a shaft with a circumference;

a tip protector having a proximal base with a proximal opening and a distal end defining a distal opening, the needle shaft movable through the proximal and distal openings along a path between a first position with the distal point projecting distally beyond the distal end of the tip protector and a second position with the distal point proximally behind the distal end in the tip protector;

a member coupled to the tip protector and movable into the path between the distal point and the distal opening with the needle shaft in the second position so as to block the distal opening; and

a separate gasket coupled to the tip protector base proximal opening and defining a gasket opening through which the needle shaft is movable between the first and second positions;

an irregularity in the needle cannula shaft circumference a pre-determined distance from the needle cannula distal point occluding passing of the needle cannula shaft through the gasket opening.

16. (New) The apparatus of claim 15, the proximal opening sized to pass the irregularity therethrough.

17. (New) The apparatus of claim 15 further comprising a flash chamber coupled to the needle cannula at the need cannula proximal end.

18. (New) The apparatus of claim 15, the gasket being a formed in place gasket.

19. (New) The apparatus of claim 15, the gasket being comprised of an adhesive material.

20. (New) The apparatus of claim 19, wherein the gasket adhesive material is selected from the group consisting of paraffin, polyester and polyamide.
21. (New) The apparatus of claim 19, wherein the gasket adhesive material is cured by exposure to ultraviolet light.
22. (New) The apparatus of claim 15, the member being pivotably coupled to the tip protector and slideably engaging the needle cannula shaft until the needle shaft is in the second position so as to be out of the path while the needle cannula moves from the first position toward the second position, the member pivoting into the path between the distal point and the distal opening with the needle shaft in the second position.
23. (New) The apparatus of claim 15, the irregularity in the needle cannula shaft circumference being a crimp.
24. (New) The apparatus of claim 15, the member being an anti-stick metal tab.

[REDACTED]

JOHNSON & JOHNSON MEDICAL
Internal Invention Disclosure
Proprietary



For review board use only

Page 1 of 4 pages

Date of submission:

Please Type or Print Legibly

Title: Low-cost Safety IVC				
Inventor/Co-Inventor Names(s)	Location (e.g., Arlington)	Phone Number		
Joe Chang	Arlington	X5113		
	Arlington			
	Arlington			

Answer the following questions:	Yes	No	When	Where
1. Tried experimentally or to be tried?		X		
2. Put into routine use or to be put into use?		X		
3. Described in a publication or to be published?		X		
4. Offered for sale (even if not accepted) or to be offered?		X		
5a. Divulged to anyone outside J&J or to be divulged?		X		

5b. To Whom: _____

5c. Affiliation: _____

5d. Confidentiality agreement signed? Yes ___ No ___

5e. How (verbal, written, by phone, etc.)? _____

EXHIBIT

B

What is the closest related art of which you are already aware?
[REDACTED]

Where is the location of the first description of your invention? (Include Notebook number and page numbers.)
[REDACTED]

When was the invention conceived (earliest documented point at which you had an idea of what you wanted to accomplish and a way to accomplish it)? DATE: [REDACTED]

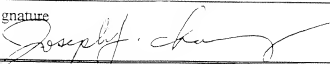

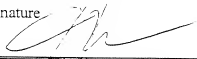

[REDACTED]

Description of Invention
(See attached Guidelines for Completion)

Please attach additional information and drawings, if appropriate

Solutions:

In a design as shown in Figure 1, a crimped partial bump is created on the cannula. A formed-in-place gasket similar to the one currently used for the PROTECTIV IVCSS is created at the bottom of the tip base. The FIPG has a resulting ID almost identical to the cannula OD, thus preventing the tip protector from further distal movement.

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Inventor/Co-Inventor Name Daniel Vincenzo	Home Address
Signature	Date
Inventor/Co-Inventor Name Don Solomon	Home Address
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Signature	Date
Witness Name	
Signature 	Date 

Submit Originals to Joe Chang, Ext. 5113

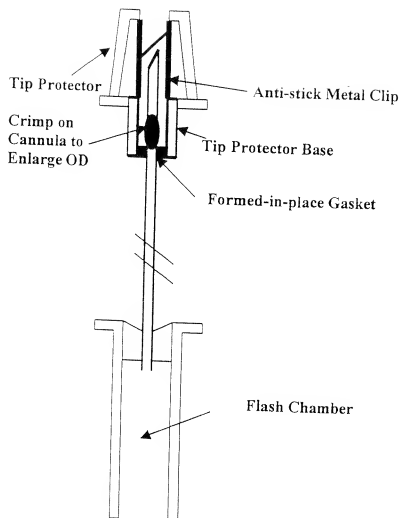


FIGURE 1